K052340

EXHIBIT 1

DEC 9 2005

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is:_____.

1. **Submitter's Identification:**

Alfa Tech Medical Systems Ltd.
5A Kaf Tet Be November St. Apt. 29
Ramat Hanassi, Bat-Yam
Israel

Date Summary Prepared: 8 August 2005

Contact Persons:

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2. **Name of the Device:**

   a. TRADE NAME: The DU857 Dual Frequency Ultrasound Therapy and Muscle Stimulator System
   b. CLASSIFICATION NAME: Ultrasound and Muscle Stimulator

3. **Common or Usual Name:** Ultrasound Diathermy/Powered Muscle Stimulator

4. **Predicate Devices Information:**

- Mettler Electronics Corp., Sonicator Plus 930, Model ME 930 (K013192)

5. **Device Description:** The DU857 Dual Frequency Ultrasound Therapy and Muscle Stimulator System is comprised of the following main components:

- A system console including software and control electronics;
- A control and display panel;
- Device accessories including Muscle Stimulator electrodes (ME2221, Mettler Corp.), ultrasound applicators (ME7513, Mettler Corp.), acoustic gel (Sonigel, Mettler Corp.) and cables, supplied by Alpha Tech.

The DU857 is a two-channel unit for therapeutic ultrasound and muscle stimulation folded into a specially designed cart. The microprocessor controlled DU857 provides Muscle Stimulator alternating current with enhanced reliability and user friendly interface. The DU857 offers 1 and 3 MHz ultrasound treatment.

The user friendly interface comprises keyboard, touch screen and audio feedback. The screen provides operator information about operation mode and signal intensities. Large control soft knobs on the touch screen make easy adjusting of power for ultrasound and muscle stimulation.

6. **Intended Use:** (Same as those for predicate device)

Therapeutic Ultrasound

1. Pain relief
2. Reduction of muscle spasm
3. Localized increase of blood flow
4. Increase range of motion of contracted joints using heat and stretch techniques.

Neuromuscular Stimulation

1. Symptomatic relief of chronic intractable pain, acute post traumatic pain or acute surgical pain
2. Temporary relaxation of muscle spasm
3. Prevention of post-surgical phlebo-thrombosis through immediate stimulation of calf muscles
4. Increase of blood flow in the treatment area
5. Prevention or retardation of disuse atrophy in post-injury type conditions
6. Muscle re-education
7. Maintaining or increasing range of motion

7. Comparison to Predicate Devices:

Comparison of technological characteristics to legally marketed predicate devices is given in the tables below:

Table 1. Comparison of general characteristics to legally marketed predicate

Item for comparison	Description		Comments
	Claimed device	Predicate device	
510K #	Pending FDA 510(k) approval	K013192	
Device Name	DU857 Dual Frequency Ultrasound Therapy and Muscle Stimulator System	Sonicator Plus 930	
Manufacturer	AlfaTech Medical Systems Ltd.	Mettler Electronics	
Intended use	Therapeutic Ultrasound and Neuromuscular Stimulation	Therapeutic Ultrasound and Neuromuscular Stimulation	
Target population	Patients who need physiotherapy treatment	Patients who need physiotherapy treatment	
Design	The concept is to combine two kind of physiotherapy units in one device	The concept is to combine two kind of physiotherapy units in one device	
Materials	Metal enclosure	Metal enclosure	
Performance	Use friendly interface, easy to operate	Use friendly interface, easy to operate	
Sterility	Sterilization is not used	Sterilization is not used	
Biocompatability	Yes	Yes	
Mechanical Safety	Compliant with mechanical safety requirements of IEC 60601-1, IEC 60601-2-5, IEC 60601-2-10 safety standards	Compliant with mechanical safety requirements of UL2601-1, CSA C22.2 NO 601.1-M90, IEC 60601-2-5, IEC 60601-2-10 safety standards	Mechanical safety requirements of IEC60601-1 and UL2601-1 are the same except additional requirements of UL2601-1 cl.55 for polymeric covers. These requirements are not applicable for DU857 System because such materials are not used.
Chemical Safety	No chemical hazards	No chemical hazards	
Human Factors	For analysis see Risk Management file		
Energy delivered	The delivered energy is limited according to requirements of collateral IEC 60601-2-5, IEC 60601-2-10 safety standards	The delivered energy is limited according to requirements of collateral IEC 60601-2-5, IEC 60601-2-10 safety standards	The maximum DU857 intensities in ultrasound and electrotherapy treatment are less than used in Sonicator Plus 930, see table 2
Compatibility with environment and other devices	The system is used inside buildings. Interaction with other devices is not performed	The system is used inside buildings. Interaction with other devices is not performed	
Used at:(hospital, home, ambulances)	Physiotherapy clinics	Physiotherapy clinics	
Standards met	IEC 60601-1, IEC 60601-2-5, IEC 60601-2-10	UL2601-1, CSA C22.2 NO 601.1-M90, IEC 60601-2-5, IEC 60601-2-10	
Electrical Safety	IEC 60601-1, IEC 60601-2-5, IEC 60601-2-10	UL2601-1, CSA C22.2 NO 601.1-M90, IEC 60601-2-5, IEC 60601-2-10	
Thermal Safety	IEC 60601-1, IEC 60601-2-5, IEC 60601-2-10	UL2601-1, CSA C22.2 NO 601.1-M90, IEC 60601-2-5, IEC 60601-2-10	
Radiation Safety	N/A	N/A	

Table 2. Comparison of technological characteristics to legally marketed predicate

General specifications		
Item for comparison	Claimed device	Predicate device
510K #		K013192
Device Name	DU857 Dual Frequency Ultrasound Therapy and Muscle Stimulator System	Sonicator Plus 930
Manufacturer	AlfaTech Medical Systems Ltd.	Mettler Electronics
Power Source	AC line	AC line
Input:	90-132VAC, 50-60Hz,4A; 207-264VAC, 50Hz, 2A	90-240VAC, 50-60Hz, 2.3A Nom
Classification	Protective Class I Equipment	Protective Class I Equipment
Year 2000 Compliant	Yes	Yes
Weight (lbs)	165	10
Dimensions (in.) HxW xL	67 in (H) x 26 in (W) x 35 in (D)	6 in (H) x 12 in (W) x 12 in (D)
Housing materials	Aluminum chassis	Aluminum chassis with ABS cover
Construction	Folded into a specially designed cart	Folded into a box shape and seams welded & ground flush and a stylized ABS cover screwed onto metal box
Operating temperature	+50°F to +86°F +10°C to +30°C	+50°F to +104°F +10°C to +40°C
Humidity	Operating, 30% to 75% Relative Humidity at 86°F Nonoperating, 20 to 80% Relative Humidity, noncondensing	Operating, 30% to 75% Relative Humidity at 104°F Nonoperating, 5 to 95% Relative Humidity, noncondensing
Storage temperature	32°F to 113°F 0°C to 45°C	-40°F to 167°F -40° C to 75°C
Timer Accuracy	± 5 seconds for all times range	±0.5 minutes for times less than 5 minutes ±10% for times from 5 to 10 minutes ±1.0 minute for times greater than 10 minutes
Maximum Treatment Time	30 minutes – ultrasound or combination therapy 30 minutes – electrical stimulation	30 minutes – ultrasound or combination therapy 60 minutes – electrical stimulation
Treatment Timer	Treatment time counts down to zero when a time is set, or up to 30 minutes when no time is set. The digital timer indicates the remaining or elapsed treatment time during the "Hold" period.	Treatment time counts down to zero when a time is set, or up to 60 or 30 minutes when no time is set. The digital timer indicates the remaining or elapsed treatment time during the "Hold" period.
Neuromuscular Stimulation		
510K #		K013192
Standards		
UL544	No	No
UL2601-1-UL	No	Yes
CUL	No	No
CSA C22.2 NO 601.1-M90	No	Yes
IEC 60601-1	Yes	No
IEC 60601-2-10	Yes	Yes
FCC Part 15-B	Yes	Yes
EN-55011 (CISPR-11)	Yes	Yes
FDA, 21 CFR 1050.10	Yes	Yes
MDD 93/42EEC, Annex II	Yes	Yes
Timer settings	1-30 minutes±1%	1-60 minutes±5%
Automatic Shut Off	Yes	Yes
Number of output modes	1	3
Channel(s)	2	2
Synchronous	1&2	1&2
Reciprocal	No	Yes
Other	No	Yes
Computerized Software Provided	Yes	N/A

Constant Current	No	Yes
Constant Voltage	No	No
Max Output Current (mA)	0-36±10% mA RMS, max., 1Kohm load, Muscle Stimulator mode N/A N/A N/A N/A	0-65±10% mA RMS, max., 1Kohm load, Muscle Stimulator mode 0-50±10% mA RMS, max., 1Kohm load, premodulated and medium frequency modes 0-99±10% mA peak, max., 1Kohm load, biphasic mode 0-2500±10% mA peak, max., 1Kohm load, high volt mode 10-990±10 µA peak, 1Kohm load, microamp mode
Max output Voltage (V)	0-36±30% volts RMS, 1Kohm load, Muscle Stimulator mode N/A N/A N/A N/A	0-65±10% volts RMS, 1Kohm load, Muscle Stimulator mode 0-50±10% volts RMS, 1Kohm load, premodulated and medium frequency modes 99±10% volts peak, 1Kohm load, biphasic mode 0-500±10% volts peak, 1Kohm load, high volt mode 1.0±10% volt peak, 1Kohm load, microamp mode
Frequency range	4800-5050 Hz ±1%(Interferential mode) N/A	4000-4250 Hz ±1%(Interferential and Premodulated modes) 2500 Hz ±2%(Medium frequency mode)
Electrodes	ME2221	ME2221
Waveforms & Channels		
All Channels	Interferential	Premodulated, Medium Frequency, Biphasic
Channel 1 & 2	Muscle Stimulator	Muscle Stimulator
Channel 1	Muscle Stimulator	Combination Therapy and all others
Channel 2	Muscle Stimulator	All
Output Displays	Two simultaneously, amber channel active indicators	Two simultaneously, amber channel active indicators
Channel Isolation	Yes	Yes
Line Current Isolation	Yes	Yes
Automatic Overload Trip	Yes	Yes
Current/Voltage level	50 mA RMS, Muscle Stimulator mode N/A	70 mA RMS, Muscle Stimulator mode 55 mA RMS, premodulated and medium frequency mode
Automatic No Load Trip	Yes	Yes
Patient Override	None	None
Control Method	On/Off	On/Off or hold
Max Leakage Current (µA)		
Chassis	<100	<100
Electrodes	<100	<100
Indicator Display Unit Functioning	Yes	Yes
Low Battery Indicator	N/A	N/A
Therapeutic Ultrasound		
510K #		K013192
Standards		
UL544	No	No
UL2601-1-UL	No	Yes

CUL	No	No
CSA C22.2 NO 601.1-M90	No	Yes
IEC 60601-1	Yes	No
IEC 60601-2-5	Yes	Yes
FCC Part 15-B	Yes	Yes
EN-55011 (CISPR-11)	Yes	Yes
FDA, 21 CFR 1050.10	Yes	Yes
MDD 93/42EEC, Annex II	Yes	Yes
Ultrasonic Generator Specifications		
Frequency	1 MHz±5% 3 MHz±5%	1 MHz±5% 3 MHz±5%
Modes	Continuous	Continuous Pulsed – 20% duty cycle Pulsed – 50% duty cycle
Pulse Repetition Rate	Not applicable	100 Hz±20%
Pulse Duration	Not applicable	2 msec±20%, 20% duty cycle
Temporal Peak/average intensity ratio	Not applicable	5:1±20%, 20% duty cycle 2:1±20%, 50% duty cycle
Maximum Output Power	7.5 W with a 5 cm^2 applicator, (ME 7513)	11 W with a 5 cm^2 applicator, (ME 7513)
Maximum Intensity	1.5 W/cm^2	2.2 W/cm^2
Indication Accuracy	±20% (for any level above 10% of maximum)	±20% (for any level above 10% of maximum)
Ultrasonic Applicator Specifications		
Piezoelectric Disks	The output transducer utilizes a barium titanate disc with a specially coated face	The output transducer utilizes a barium titanate disc with a specially coated face
Applicator Part Number	ME7513	ME7513
Frequency	1 or 3 MHz±5%	1 or 3.2 MHz±5%
Effective Radiating Area	5 cm^2±10%	5 cm^2±10%
Maximum Beam Non-Uniformity Ratio	6:1	6:1

8. <u>Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows</u>: Not applicable

9. <u>Discussion of Clinical Tests Performed:</u> Not applicable

10. <u>Conclusions:</u>

The DU857 Dual Frequency Ultrasound Therapy and Muscle Stimulator System has the same intended use and similar characteristics as the predicate device, the Sonicator Plus ® 930, Model ME 930 device. Moreover, bench testing and non-clinical testing documentation supplied in this submission demonstrates that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the Alfa Tech Medical Systems Ltd. DU857 Dual Frequency Ultrasound Therapy and Muscle Stimulator System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 9 2005

Alfa Tech Medical Systems, Ltd.
c/o Ms. Susan D. Goldstein-Falk
Official Correspondent
mdi Consultants, Inc.
55 Northern Blvd., Suite 200
Great Neck, New York 11021

Re: K052340
Trade/Device Name: The DU857 Dual Frequency Ultrasound Therapy and Muscle Stimulator System
Regulation Number: 21 CFR 890.529
Regulation Name: Ultrasound and Muscle Stimulator
Regulatory Class: II
Product Codes: IMG, IMI, IPF, LIH
Dated: November 22, 2005
Received: November 23, 2005

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit B

510(k) Number (if known): K052340

Device Name: The DU857 Dual Frequency Ultrasound Therapy and Muscle Stimulator System

Indications For Use:

Therapeutic Ultrasound:

1. Pain relief
2. Reduction of muscle spasm
3. Localized increase of blood flow
4. Increase range of motion of contracted joints using heat and stretch techniques.

Neuromuscular Stimulation:

1. Symptomatic relief of chronic intractable pain, acute post traumatic pain or acute surgical pain
2. Temporary relaxation of muscle spasm
3. Prevention of post-surgical phlebo-thrombosis through immediate stimulation of calf muscles
4. Increase of blood flow in the treatment area.
5. Prevention or retardation of disuse atrophy in post-injury type conditions
6. Muscle re-education
7. Maintaining or increasing range of motion

Prescription Use __X__
(Per 21 CFR 801 Subpart D)

OR

Over-The Counter Use_____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off) of CDRH, Office of Device Evaluation (ODE)

Division of General, Restorative, and Neurological Devices

510(k) Number K052340